

**REMARKS**

Claims 1-4, 6-10 and 12-16 are pending in this application, of which claims 1 and 8 have been amended. Claims 5, 11, 17-30 are cancelled. Based on the foregoing amendments and following remarks, reconsideration and allowance of the application is respectfully requested.

**Claim Rejections-35 U.S.C. §112**

Claims 6 and 12 stand rejected under 35 U.S.C. §112, second paragraph, as being indefinite for allegedly failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. In particular, the office action alleges that claims 6 and 12 are unclear, because the individual cross-sectional profiles appear to be different from the combined cross-sectional profile. Applicants respectfully traverse this rejection, since the claim limitation that the combined cross-sectional profile having a radius substantially equal as the individual cross-sectional radius is clearly disclosed and fully supported by the specification and drawings. For example, the following paragraphs of the specification disclose:

Page 2, line 18 to page 3 line 2:

"The first and second rigid members, when the device is in the collapsed state, can have a combined cross-sectional profile that is substantially the same as each of the individual cross-sectional profiles of the first and second rigid members, when the device is in the deployed state. For example, *the combined cross-sectional profile can be circular, and the individual cross-sectional profiles can have an arcuate shape, in which case, the radius of the circular profile can be substantially equal to the radius of curvature of each of the individual cross-sectional profiles.* Thus, it can be appreciated that the interposition of the ribs provides a smaller combined profile for the members, while not substantially reducing the shear strength of the individual members during deployment of the device."

Page 10, lines 6-11, referring to FIGS. 4 and 5:

"Specifically, the combined cross-sectional profile of the members 102 is about the same as the individual cross-sectional profiles of the members 102 when the device 100 is placed in the deployed state. As can be seen, the combined cross-sectional profile is a circle having a radius  $r$ , and the individual cross-sectional profiles are circles having radii  $r_1$ ,  $r_2$ , wherein the radius  $r$  is approximately equal to the radii  $r_1$ ,  $r_2$ ."

As can be seen from the above-quoted passages, and as depicted in FIGS. 4 and 5, the individual cross-sectional profiles of embodiments the distal portion members have approximately equal radius to the combined cross-sectional profile radius of the distal portion members.

As such, Applicants respectfully request withdrawal of the indefiniteness rejection of claims 6 and 12.

Additionally, the office action alleges that the device of Foley is deemed to possess the cross-sectional profiles recited in claims 6 and 12. Applicants respectfully disagree, since as it can be appreciated in the cross-sectional FIGS. 3, 4 and 16 of Foley, the device depicted in Foley does not have arcuate shape. Even if Foley would be modified, the "radius" of the combined cross sectional arms of Foley is approximately one and a half time larger than the radius of the individual arms as seen in FIGS. 3, 4 and 16.

#### Claim Rejections - 35 U.S.C. §103

Claims 1-4, 6-10 and 12-16 stand rejected under 35 U.S.C. § 103(a) for allegedly being unpatentable over U.S. Patent No. 6,193,757 ("Foley"). In particular, the Examiner has asserted that it would have been obvious to one skilled in the art to construct the device described in Foley with more ribs on both arm members. Applicants respectfully

request reconsideration and withdrawal of this rejection in view of the amendments made to the claims herein.

Under 35 U.S.C. §103(a), to establish a prima facie case of obviousness of a claim, all of the claim limitations must be taught or suggested, and all words in a claim must be considered in judging the patentability of that claim against Foley. In addition, there must be some suggestion or motivation to modify Foley, and a reasonable expectation of success. The mere fact that Foley can be modified does not render the resultant modification obvious to do, unless the reference or some other source (of which none has been presented by the Examiner) also suggests the desirability of making the modification. Further, if a proposed modification would render the prior art being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. Applicants respectfully submit that Foley cannot support the rejection in view of these requirements.

Foley discloses a vertebral spacer device comprising *"a main body portion and laterally expandable portions movable coupled thereto."* (Col. 9, lines 43-49, Col. 6, lines 53-65) (Emphasis added). The device of Foley comprises a ***single piece*** having two portions or arms movable coupled to the main body portion via hinge portion. A tampering guide 88 protrudes from the first arm and the second arm comprises a recess 86 to receive the tampering guide 88 when the vertebral spacer is in a closed position (Col. 8 lines 13-26, Figs 13-16). The office action alleges that Figs 13-16 of Foley depict a device having a plurality of ribs; however, even if the walls of the second arm portion surrounding the recess can be considered "ribs", there is no suggestion of motivation in Foley that the first arm portion could comprise more than one such "rib".

Further, Foley's device is not suitable for having a plurality of ribs, as recited in claims 1 and 8 of the present invention. Rather, Foley's device is intended to have a single tapered guide protrusion in the first arm with a recess in the second arm also forming a tapered surface. The tapered surfaces 87 and 89 (Fig. 17) of the first and second arms, respectively, allow the insertion tool distal end 316 to press and push uniformly against the surfaces to expand Foley's device to its deployed configuration. (Col. 9, lines 35-52). Having a plurality of ribs in the first and second arms would render the device of Foley unsatisfactory for its intended purpose, since a plurality of ribs would compromise the uniformity of the tapered surfaces 87 and 89, against which the insertion tool presses and pushes. Thus, there is no suggestion or motivation to make the proposed modification of Foley.

Furthermore, claims 1 and 8 have been amended to recite that the device is configured to be placed in a collapsed state by engaging the first and second plurality of ribs in an interposed arrangement, *with the respective proximal portions of the first and second members spaced apart from each other*, and further configured to be placed in a deployed state by disengaging the first and second plurality of ribs, *with the respective proximal portions of the first and second members moved towards each other*. In contrast, Foley's vertebrae spacer is inserted into a vertebra in a closed position using **a separate device** or insertion tool operable to expand the vertebrae spacer device to its deployed configuration when the distal end of the insertion tool presses and pushes against the internal surfaces of the vertebrae spacer, as indicated above. The insertion tool is located through a threaded opening in the hinge portion of the vertebrae spacer of Foley. (Col. 6, line 16 to Col. 7, line 42, Col. 9, lines 15- 52). Therefore, the device

disclosed in Foley is not suitable to be in a collapsed state with the proximal portions of its arms spaced apart from each other, nor to be in a deployed state with the proximal portions of its arms moved adjacent to each other. Rather, Foley's device needs an insertion tool in order to expand the vertebrae spacer into a deployed configuration. The relative positioning of the proximal portions of the arms of the Foley device plays no part on whether the device is in a collapsed or deployed configuration. Moreover, Foley's proximal arms portions are not configured to move relative to each other, since the hinged portion of the device will not allow such movement. (See FIGS 13-16 of Foley). Foley does not disclose the device and method recited in claims 1 and 8 of the present application, and there is no suggestion or motivation to modify Foley to achieve such claimed device and method. Certainly, Foley does not suggest that having the proximal portions of its device arms spaced apart from each other or moved toward each other would be effective to collapse or deploy the vertebrae spacer, or otherwise desirable.

For at least these reasons, Applicants respectfully submit that independent claims 1 and 8, as well as claims 2-4, 6-7, 9-10 and 12-16 which depend therefrom, are allowable over Foley and request withdrawal of the §103 rejection of these claims.

## CONCLUSION

In view of the foregoing amendments and remarks, Applicants respectfully submit that all pending claims are allowable over the cited prior art. Accordingly, a notice of allowance is respectfully requested. If the Examiner believes that a telephone interview could expedite resolution of any remaining issues, he is encouraged to contact Applicants' undersigned representative at the phone number listed below.

Respectfully submitted,  
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